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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,388	03/01/2002	Allen Comer	STRATA-06948	6268
72960	7590	05/30/2008	EXAMINER	
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			LANKFORD JR, LEON B	
			ART UNIT	PAPER NUMBER
			1651	
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			05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,388	Applicant(s) COMER ET AL.	
	Examiner Leon Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's arguments have been considered and are not found to be persuasive. Written description is required for methods of use of a product as well as products *per se*.

Applicant points to the Comer declaration and the statements therein to say that "that one of skill in the art could identify additional irritant responsive reporter genes" which would appear to be an argument against a enablement rejection- applicant is reminded that the written description requirement of 35 USC 112 has been deemed to be separate from the enablement requirement. The question at hand is not whether applicant has provided enablement for one to test whether or not a gene construct is irritant responsive but whether or not applicant has provided adequate written description to show possession of the generic assay which utilizes the generic "irritant responsive reporter gene construct."

The breadth of the instant claims needs to be considered when determining what is properly described. Applicant generically claims a method of using an irritant responsive reporter gene construct and the genus encompassed is extremely broad in that the term "irritant" is extremely broad. The amount of known and unknown genes that would be considered responsive to an "irritant" would have to be considered vast and thus the genus now claimed is vast. This is further evidenced by applicant's argument (and cited art) that there are many things that can be considered irritants and have an affect on the transcription of many different cellular genes. The examiner has

contended that the limited showing is insufficient to satisfy the written restriction requirement for the claimed genus. The structure of one or two irritant responsive promoter does not provide guidance to the existence or structure of other usable promoters. As such, there would appear to be no common attributes (sequence similarities, *per se*) that one of ordinary skill in the art would recognize in order to link members of this genus. Applicant argues citing the Comer declaration that “one of skill in the art would conclude that the Inventors were in possession of the necessary common attributes possessed by the members of the genus” but applicant does not appear to identify these “necessary common attributes” instead arguing that other “irritants” affect the transcription of other cellular genes which are not discussed to share common attributes or structure with IL-8 or IL 1- α .

In an unpredictable art in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only a species within the genus. *See Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Though applicant discloses two species, given that no structural requirement of the genus has been disclosed, the genus claimed is so widely variant that two species can not be considered a representative number absent the discussed necessary attributes or structure.

Claim Objections

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims using “a skin equivalent comprising a irritant responsive reporter gene construct” but the specification lacks description to convey that applicant has possession of the claimed invention. Applicant identifies 2 genes as being “irritant responsive“ which is insufficient to describe an entire genus, i.e. “irritant responsive gene(s)” particularly since applicant intends for the phrase “irritant responsive gene” to encompass unknowns.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or

disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406

A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus the genus could not be defined by function because function only disclosed what chemical structure did rather than what the chemical structure was. The Court went on to state “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Lilly*, 119 F.3d at 1569.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Leon B Lankford Jr
Primary Examiner
Art Unit 1651